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Presentation of new clinical data for KidneyIntelX

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KidneyIntelX^{TM} Clinical Results Presented at World Congress of Nephrology
Demonstrate Improved Prediction of Kidney Function Over Standard of Care

Data highlights strength of KidneyIntelX for clinical use in early-stage diabetic kidney disease patients beyond commonly used markers UACR and historical eGFR change over time

NEW YORK, NY and SALT LAKE CITY, UT February 24, 2022 - Renalytix plc **(NASDAQ: RNLX) (LSE: RENX)** today announced the presentation of new clinical data for KidneyIntelX^{TM} bioprognostic^{TM} testing at the World Congress of Nephrology Annual Meeting. The results provide robust prognostic information demonstrating the value of KidneyIntelX to predict the future rate of decline in kidney function compared with current standard diagnostics in patients with early-stage chronic kidney disease and type 2 diabetes (diabetic kidney disease), including estimated glomerular filtration rate (eGFR), urine albumin-creatinine ratio (UACR), and eGFR slope.

Advanced risk assessment tools, such as KidneyIntelX, enable primary care physicians to make optimized treatment decisions through accurate determination of individual patient risk and provide the opportunity to change intensity of care management based on that risk. In the short term, KidneyIntelX can more efficiently assess the integrated impact of changes in key risk factors (glucose, blood pressure, and albuminuria) on overall kidney health, which often do not manifest in kidney function improvements for several years.

"The key takeaway is that historical measurements commonly used today to understand kidney disease do not provide a clear picture of the future," **said Steven Coca, DO, MS, Icahn School of Medicine at Mount Sinai and Co-Founder, Renalytix.** "*Without KidneyIntelX, it is very difficult for physicians, especially busy primary care physicians, to really understand how quickly a patient's kidney disease will progress, which can contribute to confusion and undertreatment."*

The data results presented also showed the ability to use KidneyIntelX in conjunction with clinical features to reinforce the beneficial effects of new therapeutics in the same

population.

"Enabling optimal pharmacy management via KidneyIntelX may ultimately decrease hospital admissions, emergency room visits, dialysis and kidney failure risks," **said Tom McLain, President, Renalytix.** *"Most importantly, KidneyIntelX can help improve the quality of life for patients by enabling primary care physicians to mitigate risk at the earliest stages of kidney disease."*

KidneyIntelX is the only early-stage, bioprognostic solution for kidney health, and has received Breakthrough Device Designation from the U.S. Food and Drug Administration.

2022 World Congress of Nephrology presentations are available for download at: https://www.kireports.org/issue/S2468-0249(22)X0004-1

Highlights from the abstracts are as follows:

Abstract WCN22-0561: "Added Value of KidneyIntelX for Predicting Future Kidney Function Decline Compared with Historical eGFR Trajectories"
- Traditional kidney metrics, such as high albuminuria or low estimated eGFR, or historical rate of eGFR decline, do not adequately determine "future progression" of kidney disease
- The independent prognostic value of KidneyIntelX was assessed for future outcomes above and beyond traditional kidney metrics
- The KidneyIntelX risk score provided robust prognostic information for future eGFR trajectories and adverse kidney outcomes beyond ascertainment of baseline kidney function, glomerular injury, or historical kidney function trajectories
- This shows additional utility of KidneyIntelX for clinical care risk stratification and enrichment for clinical trials beyond commonly used measures

Abstract WCN22-0564: "Association of Changes in Modifiable Factors with Changes in KidneyIntelX Risk Scores in the CANVAS Participants with Prevalent Diabetic Kidney Disease"
- Prior analyses from the CANVAS trial cohort have shown that changes in a patient's KidneyIntelX score over time were informative of prognosis above and beyond the baseline KidneyIntelX score
- The associations between changes in common clinical treatment targets such as systolic blood pressure (SBP), HbA1c, and UACR with early improvements in kidney health, as measured by KidneyIntelX, were not previously explored
- Longitudinal improvements to target SBP, HbA1c and UACR resulted in meaningful and robust changes in the KidneyIntelX risk score, particularly in individuals randomized to canagliflozin, in this post hoc analysis
- In sum, these data suggest that KidneyIntelX can be used in conjunction with clinical features to reinforce the beneficial effects accrued from the treatments in patients with DKD

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About Kidney Disease

Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, or 37 million people, currently have chronic kidney disease (CKD). Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and one out of two people with very low kidney function who are not on dialysis do not know they have CKD.[1] kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease kills more people than breast and prostate cancer.[2] Every day, 13 patients in the United States die while waiting for a kidney transplant.[3]

About Renalytix

Renalytix (NASDAQ: RNLX) (LSE: RENX) is the global founder and leader in the new field of bioprognosis[TM] for kidney health. The company has engineered a new solution that successfully enables early-stage chronic kidney disease, progression risk assessment. The Company's lead product, KidneyIntelX, has been granted Breakthrough Designation by the U.S. Food and Drug Administration and is designed to help make significant improvements in kidney disease prognosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery (visit www.kidneyintelx.com). For more information, visit www.renalytix.com.

About KidneyIntelX

KidneyIntelX, is a first-of-kind solution that enables early-stage diabetic kidney diseases (DKD) progression risk assessment by combining diverse data inputs, including validated blood-based biomarkers, inherited genetics, and personalized patient data from electronic health record, or EHR, systems, and employs a proprietary algorithm to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

Sources

1.   https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html

2. https://www.nicresearch.com/clinical-research-necessary-nephrology/
3. https://optn.transplant.hrsa.gov/

Forward-Looking Statements

 Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the potential benefits, including economic savings, of KidneyIntelX, the potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether KidneyIntelX will be successfully adopted by physicians and distributed and marketed, our expectations regarding reimbursement decisions and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," and similar expressions are intended to identify forward-looking statements. We may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on our forward-looking statements. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, among others: that KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving and potential acceptance, utility and clinical practice remains uncertain; we have only recently commercially launched KidneyIntelX; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our annual report on Form 20-F filed with the SEC on October 21, 2021, and other filings we make with the SEC from time to time. All information in this press release is as of the date of the release, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

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